LEGISLATIVE SERVICES AGENCY OFFICE OF FISCAL AND MANAGEMENT ANALYSIS

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FISCAL IMPACT STATEMENT

LS 6190 NOTE PREPARED: Jan 19, 2009

BILL NUMBER: SB 305 BILL AMENDED:

SUBJECT: Substitution of Anti-epileptic Drug.

FIRST AUTHOR: Sen. Miller BILL STATUS: As Introduced

FIRST SPONSOR:

FUNDS AFFECTED: X GENERAL IMPACT: State and Local

DEDICATED
X FEDERAL

<u>Summary of Legislation:</u> This bill prohibits a pharmacist from substituting another brand name or generic anti-epileptic drug unless the pharmacist receives consent from specified individuals.

Effective Date: July 1, 2009.

Explanation of State Expenditures: *Summary:* This bill would be expected to reduce the amount of Medicaid savings realized as a result of generic substitution by reducing the rate of generic substitution within the Medicaid program. For the same reason, the bill could also potentially increase the cost of state employees' health insurance.

The bill would require that a pharmacist contact the prescribing practitioner and the consumer or the consumer's legal guardian for approval to substitute a generic anti-convulsant drug for a brand-name drug or for a generic from a different manufacturer. Currently, the Medicaid program requires generic substitution unless the prescribing practitioner has indicated that the brand-name drug is medically necessary. The bill does not specify that this provision is restricted to the use of the drugs for patients diagnosed with epilepsy or other seizure-related disorders. Requiring the pharmacist to contact the prescribing practitioner for all anti-convulsant drug orders would be anticipated to either increase the amount of time necessary to fill a prescription for this classification of drugs or increase the number of more expensive brand-name drugs dispensed due to convenience.

Medicaid Impact- Anti-epileptic drugs are classified as anti-convulsant drugs according to OMPP pharmacists. During FY 2008, the Medicaid fee-for-service program spent \$33.4 M (\$12.4 M in state General Funds) for anti-convulsant drugs, or about 15.5% of the total fee-for-service drug expenditure. OMPP

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reported there are annually about 312,000 fee-for-service claims for anti-convulsant drugs; the average payment per claim is \$102.80. Specific Medicaid generic dispensing data for anti-convulsant drugs are not available at this time.

The Medicaid program reports that each 1% increase in the generic drug dispensing rate results in \$650,000 in savings to the state. A decrease in the generic drug dispensing rate would be expected to result in a corresponding increase in expenditures.

The Medicaid risk-based managed care program (RBMC) is estimated to spend a total of \$240 M annually for drugs. The anti-convulsant drug class expenditure is reported to be \$14.2 M, or \$5.3 M in state General Funds. Changes in expenditures that occur within the capitated contracts of the RBMC program do not immediately affect Medicaid expenditures. Increases occur when the contracts and capitated rates are renegotiated. Federal law requires the capitated contracts to be actuarially sound, so any increases in the managed care organizations' costs are eventually passed along to the state.

State Employee Anthem Health Plan- As of September 2008, 29,578 state employees were enrolled in an Anthem program with 34,205 dependents, for a total of 63,783 members. Anthem reported that annually, \$2.4 M is spent for anti-convulsant drugs by state employees and the state benefit plan, or about 2.4% of the total state employee drug expenditure. Anthem reported there are annually about 20,500 claims for anti-convulsant drugs; the average cost per claim is \$116.68. If it becomes more difficult for pharmacists to fill drug orders with the less costly generics, state employees and the state benefit plans may see an increase in the cost of drugs. The potential impact to the state benefit plans may be mitigated by the fact that state employees may be more price sensitive than Medicaid and CHIP participants due to the use of copayments and deductibles in the private plan.

Also, any increase in costs in the state employee health benefit plans may not necessarily imply additional budgetary outlays since the state's response to increased health benefit costs may include (1) greater employee cost-sharing in health benefits; (2) reduction or elimination of other health benefits; and (3) passing costs onto workers in the form of lower wage increases than would otherwise occur.

Background Information-

Prescriptions: Currently, prescribing practitioners determine if a prescription must be filled as written by writing or orally indicating "brand medically necessary" on the order. If the prescription does not include that order, the practitioner has expressed permission to allow generic substitution. Indiana law currently allows generic substitution if the prescribing practitioner signs the prescription on the line indicating the pharmacist "may substitute" unless the prescription is filled under the Medicaid or CHIP programs, in which case generic substitution is required unless the prescribing practitioner writes the words "brand medically necessary" on the form. Prescriptions currently do not indicate the diagnosis for which the prescription is being ordered.

Off-label Prescribing: When a drug is prescribed "off-label," it is being prescribed to treat a condition other than the one(s) for which the drug had been approved by the FDA. This is routine practice that occurs across all therapeutic classes. A majority of drugs used for the treatment of epilepsy also have numerous approved uses beyond seizure control including pain management, anxiety, panic disorders, insomnia, bipolar disorder, alcoholism, glaucoma, congestive heart failure, and edema.

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Explanation of State Revenues:

Explanation of Local Expenditures: Local government groups enrolled in the Local Unit Government Employees (LUG) health plan may experience increased costs. LUG participants have the same benefits as state employees, but are part of a separate risk pool. For 2008, there were 22 local government groups enrolled covering about 105 employees.

In addition, school corporations and local governments purchasing health benefit coverage on their own could incur increased premiums. The specific impact is indeterminable, but would depend on current health care coverage. It is unknown if local units would cover this cost or pass the cost on to employees, as cost sharing of health benefit premiums varies widely by locality.

Explanation of Local Revenues:

State Agencies Affected: All

Local Agencies Affected: Local governments and school corporations.

<u>Information Sources:</u> OMPP, Wellpoint Inc., *Issue Brief, Restricting Generic Substitution of Drugs to Treat Epilepsy*, from the Academy of Managed Care Pharmacy, American Pharmacists Association, Generic Pharmaceutical Association, National Alliance of State Pharmacy Associations, and Pharmaceutical Care Management Association; and the American Epilepsy Society Position Statement on the substitution of different formulations of anti-epileptic drugs for the treatment of epilepsy at: http://www.aesnet.org/index.cfm?objectid=77B10758-E7FF-0F41-2C82BE234AB8CD24.

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